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(71) Applicant: SANWA KAGAKU KENKYUSHO CO., LTD.
No. 35, Higashi-sotobori-cho
Higashi-ku Nagoya-shi Aichi-ken (JP)

(72) Inventor: Sawai, Kiichi
36-14, Ninomiya 1-chome
Funabashi-shi Chiba-ken (JP)

Kurono, Masayasu
6-7 Sasaonishi 3-chome Touincho
Inabe-gun Mie-ken (JP)

Mitani, Takahiko
881-3, Ageki Hokuseicho-oaza
Inabe-gun Mie-ken (JP)

Nakano, Kasumasa
881-3, Ageki Hokuseicho-oaza
Inabe-gun Mie-ken (JP)

Asai, Hiromoto
1-6 Nakayamacho 5-chome Mizuho-ku
Nagoya-shi Aichi-ken (JP)

Ninomiya, Naohisa
5-79 Motoyagoto Tenpaku-ku
Nagoya-shi Aichi-ken (JP)

(74) Representative: Diamond, Bryan Clive et al
Gee & Co. Chancery House Chancery Lane
London WC2A 1QU (GB)

(54) Use of phytic acid or a salt thereof for treating or preventing diabetic diseases.

(57) Phytic acid or a salt thereof is known for pharmaceutical use; they are now administered orally as a preventive or treatment for diabetic diseases, especially diabetes. Suitable non-toxic salts are metal salts and salts of an organic base, a basic amino acid or an organic ester residue.

Phytic acid or a salt thereof is also of benefit to normal individuals in that it reduces body smells such as bad breath and perspiration smells.

The phytic acid or salt may be contained in a foodstuff, confectionary, liquid or pharmaceutical type of composition. A daily dose of 1-100 mg per kg body weight is suitable.

EP 0 342 955 A2

Description

USE OF PHYTIC ACID OR A SALT THEREOF FOR TREATING OR PREVENTING DIABETIC DISEASES

The present invention relates to the use of pharmaceutic material for alleviating diabetic diseases, particularly preventing and curing diabetes, which contains phytic acid or a salt or salts thereof as an effective component, and also relates to a functional diet which comprises phytic acid and/or a salt or salts thereof in a food or drink.

Sugar metabolic disease or diabetes is a disease that is induced by imbalanced meals and obesity by way of genetic dispositions and, if allowed to continue, is further complicated by vascular disorders or other secondary diseases.

The treatments for such diseases are carried out with a view to normalizing sugar metabolism, suppressing the progress thereof and preventing complications, especially vascular complications. In such treatments, (1) appropriate dietary cures, (2) the administration of insulin and orally administrable diabetic medicines and (3) the administration of medicines to remedy the secondary complications are applied in combination.

Phytic acids are found widely in plants as calcium and magnesium salts and sometimes a potassium salt. For instance, rice bran contains as high as 9.5 to 14.5 % of phytic acid, and provides a starting material for commercial phytic acid and myoinositol derived therefrom.

Phytic acid and its salt have been used for many purposes in pharmaceutical applications, calcium phytate has been used as a calcium augmentor, rice bran itself and sodium phytate as a preventive for calcium calculuses, and potassium phytate for the treatment of hyper-calcemia and hyper-calciurea of sarcoidosis patients. They have also been utilized in various other fields as fermentative aids for brewing sake and wine, metal removers making use of the chelating action of phytic acid, antioxidants in the presence of iron and calcium ions and anticorrosives for metals.

However, it has not been reported to date that phytic acid and its salts may be effective in lowering blood sugar and be used as preventatives and remedies for arteriosclerosis which is a diabetic complication.

A general object of the present invention is to provide a use of pharmaceutical materials which are effective in lowering blood sugar, remedies and preventives for arteriosclerosis or other complications caused by diabetes, and to provide functional diets for healthy as well as sick individuals to promote health.

The inventors have discovered that when orally administered, in the process of nutrition experiments, phytic acid serves to reduce body smells, especially bad breath, perspiratory smell and urinous smell. In particular, detailed studies of the effects of removal of garlic breath has revealed that this is accomplished by the enzymatic inhibition or biometabolism promotion caused by phytic acid, and has further indicated that phytic acid is effective for the inhibition of glycosuria and in lowering lipid levels.

Accordingly, the present invention provides use of phytic acid or a salt thereof for treating or preventing diabetic diseases.

The present invention also provides use of phytic acid or a salt thereof in a functional diet for healthy individuals or individuals with diabetic diseases.

The present invention relates to the alleviative, remedial and preventive effects obtained when phytic acid and its salt(s) are applied to the processes of sugar metabolism in humans, especially those with diabetes and arteriosclerosis, which is a diabetic complication and to functional diets making use of such effects. Phytic acid and its salts are so tasteless and odorless that their oral administration is easy, in liquid or solid form in various preparations. Thus, they may be expected to produce their effects by being mixed with edible substances or liquids or sprinkled over or blended with meals and then orally administered, or orally administered in the form of powders or granules.

According to the present invention, phytic acid and its salt(s) may be suitably administered to humans, generally adults, in a dosage of 1 to 100 mg/kg/day, although this depends upon the conditions of patients and the type of preparations.

The phytates usable in the present invention may include harmless metal salts as well as harmless salts with organic salts, basic amino acids and organic ester residues such as those represented by potassium phytate, sodium phytate, ammonium phytate, arginine phytate, ornithine phytate, lysine phytate, histidine phytate, monoethanolamine phytate, diethanolamine phytate, triethanolamine phytate and glucamine phytate. The phytates may also take a compositional form together with or separately from phytic acid.

In various preparations, phytates and their mixtures in a pH range of 6 to 8 may generally be selectively used depending upon the purposes of pharmaceuticals as well as functional diets because of their strong acidity.

The number of moles of various bases required to adjust one mole of phytic acid to pH 6 to 8 is shown in Table 1.

Table 1

Bases	pH: 6.00	7.00	8.00
NaOH	7.34	8.21	8.94
KOH	7.34	8.23	8.94
LiOH	7.41	8.38	9.30
NH_4OH	7.61	8.55	9.45
$HOC_2HCH_2NH_2$	7.72	8.68	9.52
$(HOCH_2CH_2)_2NH$	7.54	8.45	9.31
$(HOCH_2CH_2)_3N$	7.20	8.53	12.1
N-Methylglucamine	7.62	8.49	9.25
L-Arginine	7.79	8.67	9.60
L-Lysine	8.01	8.98	10.0
L-Histidine	11.3	-	-

The compositions used in the present invention are so safe that they are continuously usable, and are effective for alleviating diabetes by their continued use or administration.

The compositions used herein, and specific examples thereof may be the same as disclosed in our EPA 89302267.3 wherein phytic acid is used as an antidote to poisoning by drugs or alcohol.

The present invention will later be described with reference to the accompanying drawings, in which:-

Figure 1 is a graph illustrating a change of free fatty acids in blood with a change in the amount of phytic acid administered, and

Figure 2 is a graph illustrating the results of induction-testing-with-time of free fatty acids after the administration of phytic acid.

Examples

The present invention will now be explained in detail with reference to the following illustrative Examples.

Example 1

Composition a

Twenty-nine (29) g of sodium hydroxide and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 6.

Composition b

Four hundred and twelve (412) g of potassium hydroxide and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 6.

Composition c

One hundred and seventy-seven (177)g of lithium hydroxide and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 6.

Composition d

Five hundred and eighty-one (581) g of ethanolamine and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 8.

Composition e

Nine hundred and seventy-nine (979) g of diethanolamine and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 8.

Composition f

One thousand eight hundred and five (1805) g of triethanolamine and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 8.

Composition g

One thousand six hundred and fifty-seven (1657) g of N-methylglucamine and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 7.

Composition h

One thousand five hundred and ten (1510) g of L-arginine and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 7.

Composition i

One thousand seven hundred and fifty-three (1753) g of L-histidine and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 6.

Composition j

One hundred and sixteen (116) g of sodium hydroxide, 478 g of potassium hydroxide, 6.08 g of potassium chloride (as a dihydrate), 157 g of disodium hydrogen phosphate (as an anhydride) and a suitable amount of refined water are added to 660 g of phytic acid (as an anhydride) to obtain a liquid adjusted to pH 9.

These compositions a to j may be powdered by crystallization or the addition of a vehicle.

These compositions a to j may also be formed into further compositions in the form of liquids or powders from which the preparations may be obtained.

Example 2

The composition j obtained in Example 1 was formed into a composition, from which various preparations were obtained.

Composition A for Preparations

Lactose is added to the composition j (containing 200 mg of phytic acid) to obtain a total of 1000 mg of a composition.

Composition B for Preparations

Lactose is added to the composition j (containing 100 mg of phytic acid) to obtain a total of 1000 mg of a composition.

Composition C for Preparations

Refined water is added to the composition j (containing 100 mg of phytic acid) to obtain a total of 1000 mg of a composition.

Composition D

Light silicic anhydride is added to the composition j (containing 200 mg of phytic acid), followed by drying, which gives a total of 1000 mg of a composition.

Production Examples of Preparations

Production Example 1 (Elixir)

Composition C	100 g	(10 g calculated as phytic acid)
Compound orange extract	24 ml	
Ethanol	400 ml	
Glycerine	400 ml	
Refined water	Total: 1000 ml	

Predetermined amounts of the aforesaid components are uniformly mixed together to obtain a colorless and clear elixir preparation. A five-milliliter dosage of this elixir preparation contains 50 mg of phytic acid.

Production Example 2 (Capsules)

Composition A	200 mg	(40 mg calculated as phytic acid)
Lactose	20 mg	
Corn Starch	38 mg	
Magnesium stearate	2 mg	

Predetermined amounts of the aforesaid components are uniformly mixed together and packed in No. 2 capsules. One such capsule contains 40 mg of phytic acid.

Production Example 3 (Granules)

Composition A	600 mg	(120 mg calculated as phytic acid)
Lactose	140 mg	
Corn starch	250 mg	
Hydroxypropylcellulose	10 mg	

Predetermined amounts of the aforesaid components are uniformly mixed together, and the mixture is then wet-granulated with water and ethanol into granules. One hundred and twenty (120) mg of phytic acid are contained in an one-gram dosage of such granules.

Production Example 4 (Powder)

The composition A is divided and heat-sealed in aluminium to obtain wrappers each of 1.5 g.

Production Example 5 (Tablet)

Composition A	100 mg	(20 mg calculated as phytic acid)
Corn starch	19 mg	
Crystalline cellulose	30 mg	
Magnesium stearate	1 mg	

Predetermined amounts of the aforesaid components are uniformly mixed together, and the mixture is then compressed into tablets each of 7 mm in diameter and 150 mg in weight. One such tablet contains 20 mg of phytic acid.

Production Example 6 (Syrup)

Composition C	50 g	(5 g calculated as phytic acid)
White sugar	300 g	
D-sorbitol(70%)	250 g	
Methyl p-oxybenzoate	0.3 g	
Propyl p-oxybenzoate	0.15 g	
Sodium citrate	10 g	
Perfume	1.5 g	
Refined water	Total: 1000ml	

Predetermined amounts of the aforesaid components are dissolved and mixed together into a colorless and clear syrup. One hundred (100) mg of phytic acid is contained in a twenty-milliliter dosage of this syrup.

Production Example 7 (Dry syrup)

Composition B	100 mg	(10 mg calculated as phytic acid)
Sodium citrate	2.4 mg	
Citric anhydride	2.2 mg	
Tragacanth powders	2.7 g	
White sugar	suitable amount	
Hydroxypropylcellulose	3.0 mg	
Perfume	slight amount	
Perfume	slight amount	

Predetermined amounts of the aforesaid components are uniformly mixed together, and are then wet-granulated with water and ethanol into a dry syrup. An one (1)-gram dosage of this syrup contains 10 mg of phytic acid.

Production Example 8 (Troche)

Composition A	100 mg	(20 mg calculated as phytic acid)
White sugar	870 mg	
Lactose	20 mg	
Magnesium stearate	10 mg	

Of the aforesaid components the composition A and white sugar are uniformly mixed together in the respective amounts of 100 g and 870 g, and are then wet-granulated with water and ethanol, followed by drying at a temperature of lower than 35° C. Added to the dried product are 20 g of lactose and 10 g of magnesium stearate to obtain troches each of 15 mm in diameter and 1 g in weight. One such troche contains 20 mg of phytic acid.

Production Example 9 (Candy)

Composition B	100 mg	(10 mg calculated as phytic acid)
White sugar	2400 mg	
Starch syrup	1500 mg	
Perfume	slight amount	

Of the aforesaid components, 240 g of white sugar and 150 g of starch syrup are mixed with 100 g of refined water. After melting by heating, the mixture is sieved for the removal of foreign matters. The resulting liquid is concentrated under pressure with the application of heat for dehydration to prepare a starch syrup dough having a moisture content of 2 to 3 % at 130 to 150° C. Added to this dough are 10 g of the composition B and a slight amount of perfume, and the product is molded to obtain candies each of 4 g in weight. Each candy contains 10 mg of phytic acid.

Production Example 10 (Magnesium Citrate Oral Solution)

Composition C	3 g	(300 mg calculated as phytic acid)
Syrup	2.5 ml	
Refined water	Total: 30 ml	

Predetermined amounts of the aforesaid components are uniformly mixed together into "limonada". A thirty (30)-milliliter dosage of such limonadas contains 300 mg of phytic acid.

Production Example 11 (Granule)

Composition D	500 mg	(100 mg calculated as phytic acid)
Garlic powders	750 mg	
Lactose	suitable amount	

Predetermined amounts of the aforesaid components are uniformly mixed together, and are then wet-granulated with water and ethanol into granules. One hundred (100) mg of phytic acid is contained in an 1.5-gram dosage of such granules.

Production Example 12 (Drinkable Solution)

Composition C	1 g	(100 mg calculated as phytic acid)
Mel	0.5 g	
White sugar	2.0 g	
Citric acid	suitable amount	
Sodium citrate	suitable amount	
Peppermint	slight amount	
Refined water	suitable amount	

Predetermined amounts of the aforesaid components were uniformly mixed together into a colorless and clear internal liquid preparation. A thirty (30)-milliliter dosage of this liquid preparation contains 100 mg of phytic acid.

Production Example 13 (Garlic Flavoring)

Composition D	0.285 g	(0.1 g calculated as phytic acid)
Avisel	0.18 g	
Garlic powders	0.75 g	
Light silicic anhydride	0.256 g	
Corn starch	sultable amounts	

Predetermined amounts of the aforesaid components are granulated by a conventional method.

Stability Testing

The preparations according to Production Examples 1 to 10 were subjected to stability testing to measure the amount of residual phytic acid. The results are set forth in Table 2.

Table 2

Amounts of Residual Phytic Acid in the Stability Testing of the Preparations According to the Production Examples (% with respect to the specified contents)

Samples	Storage Vessels	At the beginning of Storage	After 3 weeks at 60° C
P.Ex.1A*	Glass Bottle	100.5	101.2
P.Ex.2B*	PTP	101.4	99.4
P.Ex.3C*	Aluminium Wrapper	100.1	100.0
P.Ex.4D*	"	100.9	102.1
P.Ex.5E*	PTP	99.2	99.8
P.Ex.6F*	Glass Bottle	102.1	100.3
P.Ex.7G*	Aluminium Wrapper	100.6	100.1
P.Ex.8H*	Aluminium SP	99.7	100.5
P.Ex.9I*	Aluminium Bag	99.9	99.2
P.Ex.10J*	Glass Bottle	102.1	100.9
P.Ex.11K*	Aluminium Wrapper	100.3	100.1
P.Ex.12L*	Glass Bottle	100.1	99.8

A*: Erixir,
B*: Capsule,
C*: Granule,
D*: Powder,
E*: Tablet,
F*: Syrup,
G*: Dry Syrup,
H*: Troche,
I*: Candy,
J*: Limonada,
K*: Granule,
L*: Drinkable Solution.

Test Examples

1. Effect on the Suppression of Glycosuria in Mice with Alloxan Diabetes

(a) Test Animals and Procedures

Used for testing were three groups of ddy male mice each weighing about 20 g (21 to 23 g) and fasted for three hours, five per group. The testing control was intraperitoneally administered with sodium phytate in a ratio of 100 to 200 mg/kg, while the normal and control groups were dosed with physiological saline in a ratio of 10 ml/kg. The control group was also administered with alloxan in a ratio of 75 mg/kg through the tail vein. Twenty-four hours after the administration, blood was collected with the animals under etherization from the descending aorta to measure the concentration of blood sugar and ketone body (acetoacetic acid and β-hydroxybutyric acid) in plasma with an autoanalyzer (Hitachi, Model 705).

(b)Test Reagents

1) For the measurement of blood sugar, Glucose HA Test WAKO (by Wako Junyaku Co., Ltd.) was used.

2) For the measurement of acetoacetic acid, Ketone Test A Sanwa (sold by Sanwa Chemical Institute Co., Ltd.) was used.

3)For the measurement of β-hydroxybutyric acid, Ketone Test B Sanwa (sold by Sanwa Chemical Institute Co., Ltd.) was used.

(C)Test Results

The results are set forth in Table 3, from which it is found that the concentration of blood sugar tends to drop with the administration of 100 mg/kg of sodium phytate, and such a tendency turns significant with 200 mg/kg. It is also noted that the concentration of ketone body tends to drop in either case. This indicates that sodium phytate is effective to suppress glycosuria.

Table 3

	Dosage of Na Phytate in mg/kg	Sugar in mg/dℓ	Ketone Body in μmol/ℓ (1)	Ketone Body in μmol/ℓ (2)
Normal Group		189	0	114
Control Group		548±46	44	635
Test Group	100	291±117	5	194
Test Group	200	147±14	14	154

2. Induction of Lipoprotein lipase (LPL for short) - effective to cure secondary diseases developed by diabetes

(a) Test Animals and Procedures

In a range of 1 to 50 mg, sodium phytate was administered under to four groups of Wistar rats, each weighing 190 to 200 g and previously fasted for 12 hours or longer, five per group. Five minutes after the administration, blood was collected from the descending aorta. Sodium citrate was added to the collected blood to regulate its final concentration to 3 mg/ml, which in turn was centrifuged to obtain plasma.

(b)Test Procedures

The activity of LPL in the obtained plasma was determined by the measurement of liberating fatty acids. The free fatty acids were measured with NEFAC Test Wako-Kit (by Wako Junyaku Co., Ltd.).

(c)Test Results

1)The results of changes in the free fatty acids with changes in the dosage are shown in Figure 1.

By measurement, it has been found that the free fatty acids are induced depending upon the amount of sodium phytate in the range of 1 to 50 mg/kg/weight, but the animals are killed with a dosage exceeding 50 mg/kg/weight.

2) Results of Induction-with-time of Free Fatty Acids

With an intravenous injection of sodium phytate in an dosage of 20 mg/kg/weight, the maximum induction of LPL occurred five minutes after the injection, and was sustained over about 40 minutes, as can be seen from the results shown in Figure 2.

From the foregoing results, it has been found that the present invention is effective in lowering lipid levels.

3. Organoleptic Comparison Test

For organoleptic comparison testing on whether the taste, edibility and the smell are good or bad, beefsteaks cooked with 0.5 g (33 mg calculated as phytic acid) of the garlic flavoring preparation according to Production Example 13 and other seasonings were fed to a 20-member panel simultaneously with those without phytic acid. The results are shown in Table 4.

Table 4

	Indistinguishable from phytic acid-free steaks	Better than phytic acid-free steaks	Bad
Taste	6	14	0
Edibility	5	15	0
Smell	1	19	0

From the above results, it has been found that phytic acid excels in taste, edibility and smell, and is effective as a food flavoring material.

4. Organoleptic Test

Thirty (30) ml (100 mg calculated as phytic acid) of the drinkable solution of Production Example 12 was continuously administered to three diabetic patients once a day for 7 days, and a questionnaire was conducted on its drinkability and effects. The results are shown in Table 5.

Table 5

		Good	Indistinguishable
Drinkability		3	0
Effects	(a) Recovery from fatigue	2	1
	(b) Amelioration of conditions	3	0

It is here to be noted that this drinkable solution was administered to the patients, while suggesting that it was a healthy diet effective for diabetes. Although it may not be possible to deduce from such results any significant comment on the mechanism of action of phytic acid, it is believed that phytic acid is organoleptically effective as a food additive.

Claims

1. Use of phytic acid and/or a salt thereof for the manufacture of a medicament for treating or preventing diabetic diseases.

2. Use as claimed in Claim 1, wherein the diabetic disease is diabetes.

3. Use as claimed in Claim 1, wherein the diabetic disease is a diabetic complication.

4. Use as claimed in any preceding claim, wherein the salt of phytic acid is a non-toxic metal salt, or a non-toxic salt with an organic base, a basic amino acid or an organic ester residue.

5. A functional diet comprising phytic acid and/or a salt thereof in which the salt of is a non-toxic metal salt or a non-toxic salt with an organic base, a basic amino acid or an organic ester residue.

6. Use of phytic acid and/or a salt thereof in a functional diet for healthy individuals or individuals with diabetic diseases.

7. Use as claimed in Claim 6, wherein the salt is a main component in the functional diet and is a non-toxic metal salt, or a non-toxic salt with an organic base, a basic amino acid or an organic ester residue.

FIG. 1

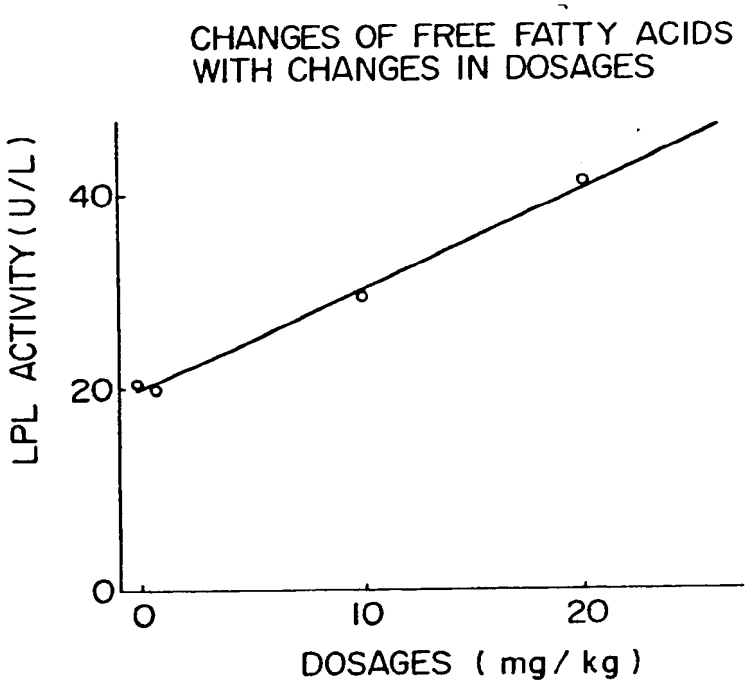
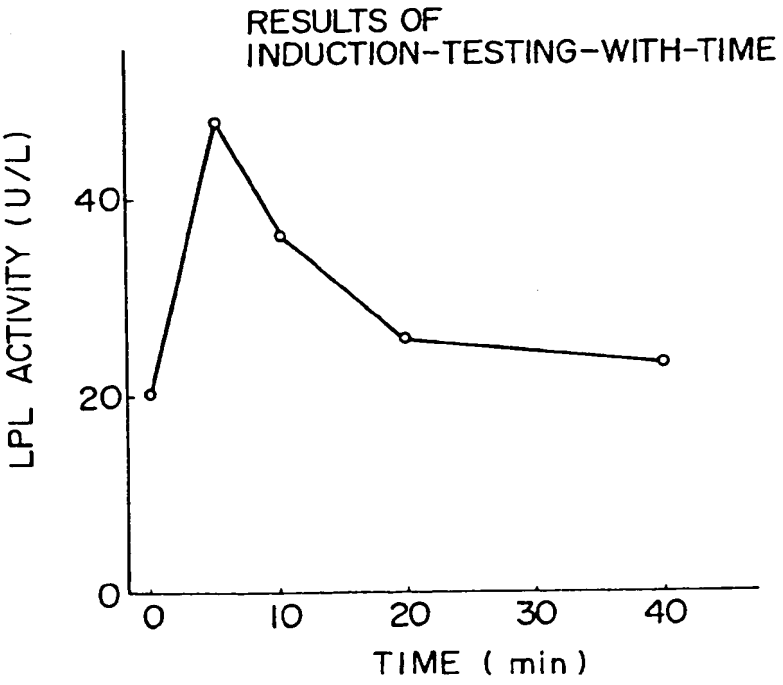

CHANGES OF FREE FATTY ACIDS
WITH CHANGES IN DOSAGES
LPL ACTIVITY (U/L)
40
20
0
0
10
20
DOSAGES (mg / kg)

FIG. 2


RESULTS OF
INDUCTION-TESTING-WITH-TIME
LPL ACTIVITY (U/L)
40
20
0
0
10
20
30
40
TIME (min)

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(71) Applicant: **SANWA KAGAKU KENKYUSHO CO., LTD.**
No. 35, Higashi-sotobori-cho
Higashi-ku Nagoya-shi Aichi-ken(JP)

(72) Inventor: **Sawai, Kiichi**
36-14, Ninomiya 1-chome
Funabashi-shi Chiba-ken(JP)
Inventor: **Kurono, Masayasu**
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Inventor: **Asai, Hiromoto**
1-6 Nakayamacho 5-chome Mizuho-ku
Nagoya-shi Aichi-ken(JP)
Inventor: **Ninomiya, Naohisa**
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(74) Representative: **Diamond, Bryan Clive et al**
Gee & Co., Chancery House, Chancery Laneane
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European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 30 4984

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X,Y	REV. CLIN. ESP., vol. 115, no. 3, 1969, pages 219-226; E. SANCHEZ LOPEZ: "Nuevos aspectos del equilibrio de membrana. Mecanismo de accion de los fitatos consecuencias practicas" * Page 224, right-hand column, lines 25-35; page 225, left-hand column, lines 55-57; page 226, left-hand column, line 42 *	1-7	A 61 K 31/66
Y	AM. J. CLIN. NUTR., vol. 46, no. 3, 1987, pages 467-473, Am. Society for Clinical Nutrition; L.U. THOMPSON et al.: "Phytic acid and calcium affect the in vitro rate of navy bean starch digestion and blood glucose response in humans1-3" * Page 470, figure 5; page 471, left-hand column, lines 3-8, right-hand column, lines 33-41; page 472, left-hand column, lines 17-30 *	1-7	
A	AM. J. CLIN. NUTR., vol. 38, no. 3, September 1983, pages 481-488, Am. Society for Clinical Nutrition, US; M.J. THORNE et al.: "Factors affecting starch digestibility and the glycemic response with special reference to legumes1-3" * Page 483, left-hand column, lines 22-27 *	1-7	
A	JOURNAL OF FOOD SCIENCE, vol. 49, no. 4, 1984, pages 1228-1229; L.U. THOMPSON et al.: "Starch digestitibility as affected by polyphenols and phytic acid" * The whole document *	1-7	
Y	EP-A-0 179 440 (SIREN MATTI) * Page 36 *	1-7	
A	NEW. ENGL. J. MED., vol. 316, no. 10, 1987, pages 599-606; D.A. GREENE et al.: "Sorbitol, phosphoinositides, and sodium-potassium-ATPase in the pathogenesis of diabetic complications" * Pages 603-604 *	1-7	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 K

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	17 July 90	GERLI P.F.M.

CATEGORY OF CITED DOCUMENTS

X: particularly relevant if taken alone
Y: particularly relevant if combined with another document of the same catagory
A: technological background
O: non-written disclosure
P: intermediate document
T: theory or principle underlying the invention

E: earlier patent document, but published on, or after the filing date
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